

# NutritionTimes

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## Soy Protein and Your Health: Facts and Myths!

Thuan L. Tran, MD, San Bernardino County Nutrition Quackery Prevention Task Force

Soybeans *are* a member of the legume family. Its protein contains all the essential amino acids and therefore can be used as a full replacement for animal protein in the human diet. In addition to being rich in protein, fiber, calcium, iron, and low in saturated fat, soybeans are also an excellent source of isoflavones.

These compounds possess weak estrogenic effects and antioxidant properties. Due to these qualities, isoflavones have been widely assumed to be responsible for the effects of soy protein on many hormone-related conditions such as certain types of cancer.

Public interest in soy products has been rising rapidly over the last decade. Sales of soy foods and supplements were \$852 million in 1992, and are projected to rise to \$3.7 billion in 2002. In October 1999, the Food and Drug Administration approved the use of the health claims on food labels regarding the role of soy protein consumption in reducing the risk of coronary heart disease. In order to use this claim, soy protein consumption must be eaten in conjunction with a diet low in saturated fat and cholesterol. Soy protein has also been promoted for a wide variety of other conditions. However, before any prudent recommendation can be made, let's review the scientific evidence regarding cardiovascular disease, cancer prevention, and women's health with the effects of soy protein consumption.

### CARDIOVASCULAR DISEASE:

Epidemiological data have strongly suggested a beneficial effect of soy protein. In Japan where cardiovascular mortality rates are 50% lower than for Americans, their average soy protein consumption is about 55 grams per day compared to less than 5 grams per day in the United States. Animal studies have shown that those on a diet containing soy protein had a better plasma lipid profile and a lower rate of atherosclerosis compared to those on an animal protein diet. Human clinical trials have yielded varying outcomes. A recent meta-analysis of 38 controlled clinical trials confirmed a positive relationship between soy protein consumption and serum lipid levels. Overall a diet high in soy protein (25 grams/day) was associated with a 9.3% reduction in total cholesterol, 12.9% reduction in LDL-cholesterol, and 10.5% reduction in triglyceride level. The effect on HDL-cholesterol was not significant. All 38 trials in this review used intact soy protein in the treatment group. Studies on isoflavone extracts, in contrast, have failed to demonstrate any significant benefit over placebo.

The American Heart Association states that daily consumption of soy protein could improve lipid profiles in people with elevated cholesterol levels. A few important points need to be emphasized in order to achieve this benefit. First, one needs to consume at least 25 grams of

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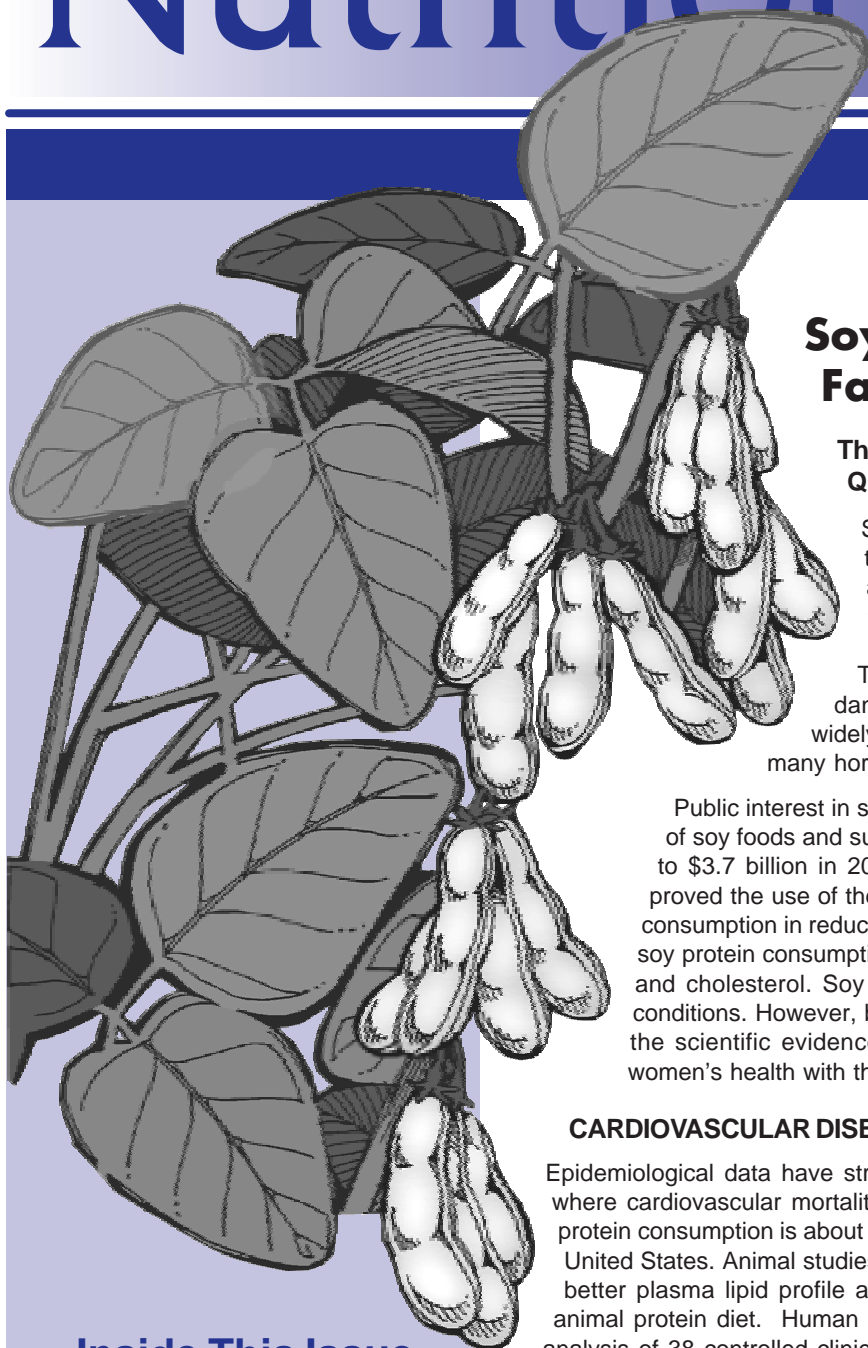
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## Federal Trade Commission (FTC) Announces Crackdown on Internet Fraud

*Ann Stahl, Investigator, FTC*

**The Federal Trade Commission announced on June 14, 2001 a new round of enforcement actions against the fraudulent marketing of supplements and other health products on the Internet.**

The FTC's action is part of a coordinated effort with the FDA, several state Attorneys General, and Health Canada to crack down on unscrupulous marketers who use the Internet to prey on the sickest and most vulnerable consumers. The six new FTC cases target companies marketing a variety of herbal products and other dietary supplements as cures or treatments for cancer, HIV/AIDS, arthritis, hepatitis, Alzheimer's, diabetes, and many other diseases.

Among the many products for which unfounded claims were being made were a DHEA hormonal supplement, St. John's Wort, various multi-herbal supplements, colloidal silver, and a variety of electrical therapy devices. Some of the marketers also claimed that their products are safe when, in fact, there may be potentially dangerous interactions with other medications.

Among the many false and unsubstantiated claims challenged in the FTC cases were promises that:

- *People could cancel their surgery, radiation, or chemotherapy in favor of herbal cures that cost hundreds of dollars;*
- *Those with HIV or AIDS could use St. John's Wort as a safe treatment for the disease. In fact, the FTC alleged, there is inadequate evidence to support the use of the herb to treat AIDS. Indeed, St. John's Wort is known to interfere with proven HIV/AIDS medications; and*
- *A device that delivered mild electric current would kill parasites claimed to cause such serious diseases as cancer and Alzheimer's.*

The Commission files complaints against companies it has reason to believe have violated the FTC Act by engaging in false or deceptive advertising. It often begins investigations by sending letters demanding substantiation for health-related claims made about products such as dietary supplements. When the FTC wins such a case, it can order the company to cease making the challenged claims. It can also ask a Federal District Court to order refunds for consumers, as well as impose civil penalties in certain cases.

### The companies that were named in the FTC enforcement actions:

**Panda Herbal International of Bensalem, PA** – Marketed Herbal Outlook, a dietary supplement containing St. John's Wort, and Herb Veil 8, a topical ointment. Panda claimed that consumers could safely use Herbal Outlook to treat such diseases as HIV/AIDS, herpes simplex, tuberculosis, influenza, and hepatitis B infections. They also claimed that Herbal Outlook has no known contraindications or drug interactions. In addition, the respondents claimed that Herb Veil 8 is effective in the treatment of carcinomas, adenocarcinomas, and melanomas. A proposed settlement order would prohibit such claims and would require Panda to place the following disclosure warning in any future ads: "WARNING: St. John's Wort can have potentially dangerous interactions with some prescription drugs. Consult your physician before taking St. John's Wort if you are currently taking anticoagulants, oral contraceptives, antidepressants, anti-seizure medications, drugs to treat HIV or prevent transplant rejection, or any other prescription drug. This product is not recommended for use if you are or could be pregnant unless a qualified health care provider tells you to use it. The product may not be safe for your developing baby." In addition, the settlement would require Panda to send a notice to all purchasers of Herbal Outlook and Herb Veil 8 informing them of the Commission's settlement, and to offer full refunds upon request to consumers who have purchased Herb Veil 8.

**ForMor, Inc. of Conway, AR** – Claimed that St. John's Kava Kava, its product containing St. John's Wort and other herbs, is effective in the treatment of HIV/ AIDS, colds, syphilis, tuberculosis, dysentery, whooping cough, mania, hypo-chondria, fatigue, and hysteria; that ingestion of colloidal silver is proven effective in treating over 650 infectious diseases, arthritis, blood poisoning, cancer, cholera, diphtheria, diabetes, dysentery, gonorrheal herpes, influenza, leprosy, lupus, malaria, meningitis, rheumatism, shingles, staph infections, strep infections, syphilis, tuberculosis, whooping cough, and yeast infections; and that its shark cartilage pills are effective in the treatment of arthritis and other degenerative and inflammatory conditions, as well as brain cancer. The proposed settlement would prohibit such claims and require disclosures similar to those included in the Panda settlement.

**MaxCell BioScience of Broomfield, CO** – Used a multi-level marketing scheme to sell Longevity Signal Formula, a dietary supplement containing DHEA, that it claimed reverses the aging process and prevents, treats, or

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## REPORTING INTO MEDWATCH!

### The Food & Drug Administrations (FDA) Adverse Event Reporting System

Laurel Eu, Public Affairs Specialist, FDA

#### Excerpted from the Office of Inspector General's Report on Adverse Event Reporting for Dietary Supplements...

Underreporting severely limits the ability of an adverse event reporting system to detect adverse events, generate signals of possible health concerns, assess those signals, and take appropriate action based on its assessment. Among the factors that may contribute to under-reporting are that

- Many consumers presume supplements to be safe,
- Many consumers use these products without the supervision of a health care professional, and
- Many consumers may be unaware that FDA regulates them.

FDA's system is limited not only by under reporting, but by resources and lack of information, including

- Limited medical information (medical records)
- Limited product information (ingredients, product labels)
- Limited manufacturer information (name of company, city, state)
- Limited information on the consumer (identifying information for injured party)

The public, manufacturers, and health professionals need to be informed about the adverse event reporting system for dietary supplements, and encouraged to report. Increased reporting is only a part of the solution; adequate resources, regulatory changes, requirements for manufacturer reporting, partnerships with organizations and improved computer tracking mechanisms are also critical parts of the solution. However, consumers and health professionals can take the first step to improve adverse event reporting system... by reporting!

#### FDA's Instructions on How to Report an Illness or Injury Associated With a Dietary Supplement

FDA can be contacted to report general complaints or concerns about food products, including dietary supplements. You may telephone or write to the FDA.

If you think you have suffered a serious harmful effect or illness from a dietary supplement, your health care provider can report this by calling FDA's MedWatch hotline at 1-800-FDA-1088 or using the website [www.fda.gov/medwatch/report/hcp.htm](http://www.fda.gov/medwatch/report/hcp.htm). The MedWatch program allows health care providers to report problems possibly caused by FDA-regulated products such as drugs, medical devices, medical foods and dietary supplements. The identity of the patient is kept confidential.

Consumers may also report an adverse event or illness they believe to be related to the use of a dietary supplement by calling FDA at 1-800-FDA-1088 or using the website [www.fda.gov/medwatch/report/consumer/consumer.htm](http://www.fda.gov/medwatch/report/consumer/consumer.htm). FDA would like to know when a product causes a problem even if you are unsure the product caused the problem or even if you do not visit a doctor or clinic.



#### The companies that were named in the FTC enforcement actions: (continued from page 2)

cures numerous age-related diseases and conditions such as atherosclerosis, arthritis, high blood pressure, elevated cholesterol levels, weight gain, and poor liver function. The company also claimed that its at-home urine test product, called the Anabolic/Catabolic Index Test, provided a clinical gauge of an individual's overall healthiness and youthfulness. The proposed settlement would prohibit such claims and would require \$150,000 in consumer redress payments.

**Aaron Company of Palm Bay, FL** – Sold Colloidal Silver, a dietary supplement allegedly containing suspended particles of silver, intended to be taken orally for the cure and treatment of more than 650 diseases ranging from cancer and multiple sclerosis to HIV/AIDS; Chitosan with vitamin C, a tablet purportedly causing weight loss without caloric restriction; and Ultimate Energizer, a product containing ephedra (ma huang) that the company marketed as a safe stimulant having no side effects. The proposed settlement would ban the unsubstantiated claims, as well as requiring a health warning disclosure in any future advertising of products containing ephedra.

**Western Herb & Dietary Products Co. of Blaine, WA** – Marketed various herbal formulas and herbal cure packages including Black Walnut Tincture, Wormwood Tincture, and Cloves Tincture to treat and cure cancer, HIV/AIDS, Alzheimer's, diabetes, and arthritis, claiming that they would make surgery and chemotherapy unnecessary; as well as a "Zapper Electrical Unit" to treat and cure Alzheimer's and HIV/AIDS. A preliminary injunction has been entered in the case, pending further adjudication of the Commission's complaint.

**Jaguar Enterprises of Texas, North Carolina, and Florida** – Sold various electronic therapy devices with such names as the Black Box, Magnetic Pulser, Magnetic Multi-Pulser, Beck-Rife unit, and Portable Rife Frequency Generator, which it claimed would cure or prevent diseases such as AIDS, cancer, arthritis, Gulf War Syndrome, and Chronic Fatigue Syndrome, by passing an electric current or magnetic pulse through the body and killing bacteria, viruses, and parasites. The company also claimed that its "Miracle Herbs" product is safe and effective in treating cancer of all types, AIDS, and bacterial and viral infections. The proposed settlement would prohibit the challenged claims, as well as any unsubstantiated claims and misrepresentations of any test, study, or research. It would also require the company to offer refunds to past purchasers of its products.



# Newsmotes

## From the FDA!

### Avoid the Dangers of Buying Drugs Online

*Rosario Quintanilla, Public Affairs Specialist, FDA*

The internet is rapidly changing the way we live, including how we work, and shop. The growth of the internet in recent years has enabled consumers to purchase medicines online. While this may be a beneficial option, it also comes with potential risks.

One must exercise caution. The number of online pharmaceutical sites seem to grow daily and many of these bypass the traditional procedures and safeguards for prescribing drugs.

Some sites sell products that are not approved by the Food and Drug Administration, or if they deal in approved products, may sidestep established procedures designed to protect consumers.

"As some illegal sites are closed down, other illegal sites spring up," says Rosario Vior, Public Affairs Specialist with the Los Angeles District Office of FDA. "The best way to protect consumers is to educate them in the do's and don'ts of safe online shopping for medical products."

While perhaps not utilizing this service now, future conditions may make this a viable option for added audiences. Illness and or physical limitations may make this an attractive option. The benefit of a confidential setting for making medical product purchases is one that may turn out to be attractive.

For additional information, go to [www.fda.gov](http://www.fda.gov) or call 888-INFOFDA.

Brochures on this subject are available free from the local FDA office by calling 949-798-7611.



If you choose to make your purchases online, the FDA recommends that you keep the following Do's and Don'ts in mind.

**DO** take only medications that have been prescribed by your doctor.

**DO** buy only from sites that require prescriptions from a physician and that also verify each prescription before dispensing the medication.

**DO** use sites that provide convenient access to a licensed pharmacist who can answer your questions.

**DO** check with your state board of pharmacy or look for the VIPPS (Verified Internet Pharmacy Practice Site) seal as an assurance that such sites meet all applicable state and federal regulations.

**DO** buy only from U.S. based sites.

**DON'T** buy from sites that sell prescription medicines without a prescription.

**DON'T** provide any personally identifiable information unless you are confident the site will protect them.

**Finally . . . .**

**DO report problems!**

If you suspect a site is not a licensed pharmacy, do not buy from it. Report the site and any complaints to the FDA at [www.fda.gov/oc/buyonline/buyonlineform.htm](http://www.fda.gov/oc/buyonline/buyonlineform.htm)

## Soy Protein and Your Health: Facts and Myths!

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soy protein a day (Table 1). Second, the protein should come from whole foods. The effect of using extracts of isoflavones or synthetic isoflavone analogs are largely unknown and are not recommended. Third, even though soy protein could reduce cholesterol and triglyceride in high-risk individuals, to date there is no concrete clinical evidence that soy protein could lower the morbidity and mortality of heart disease.

### CANCER PREVENTION:

The weak estrogenic effects of isoflavones has led to speculation that soy protein could play a role in the prevention of hormone related diseases such as breast and prostate cancer. However, clinical trials both in animals and in humans have been inconsistent in supporting the causative effect of soy protein in relation to cancer prevention. Two studies from Japan and Singapore found that consumption of soy protein was associated with a reduction in breast cancer risk. In contrast, a study in China did not find any relationship between soy protein and a reduction in the risk of breast cancer in both pre- and postmenopausal women. A case-control study on 1554 Asian women in America found that tofu consumption was related to a lowered breast cancer risk, but only in women born in Asia and not in women born in the US.

Similarly, clinical trials on the effect of soy protein on prostate cancer have shown conflicting outcomes. Most studies have shown that the risk of these diseases increases with high dietary fat and alcohol intake, and decreases with consumption of green-yellow vegetables and legumes, not just soy products. As the traditional diet of Asians become more westernized, the rate of these malignancies will continue to rise. These observations suggest that the lowered risk of cancer in Asian population was due to an overall life style with diet high in vegetable and legumes, and low in fat and alcohol rather than to a single nutrient such as soybeans.

### WOMEN'S HEALTH:

Since soybeans contain many phytoestrogens it has been promoted as a natural alternative to hormone replacement therapy in menopausal women. However,

most randomized clinical trials have not been consistent in supporting the use of isoflavones in managing menopausal symptoms, including hot flashes, headache, and anxiety. Even in studies that reported positive outcomes, the benefit was modest and the length of the trials were relatively short. In a randomized study of 104 women, subjects taking soy protein had a 45% reduction in their daily hot flashes after 12 weeks compared to a 30% reduction in the placebo group. In contrast, women treated with conventional hormone replacement therapy may expect up to 74% to 90% improvement in their symptoms.

Research on osteoporosis also failed to support the notion that soy protein could be beneficial to bone health. Both animal and human clinical trials have shown conflicting results. Most studies found no effect of isoflavones on bone mineral content. Bone density and prevalence of osteoporosis are very similar between women in Japan and in the United States. Even though the rate of hip fractures is lower in Japanese women, the rate of spinal fractures is actually higher compared to Caucasian women. Of interest is the observation that the rates of falls varied significantly among Japanese and Caucasian women, with white women fall approximately twice as often as their Japanese counterparts.

These findings suggest that the difference in hip fracture risk between Asian and Western women was mostly due to variations in hip geometry and body stature, which led to a lower risk of falls in Asian women, rather than from differences in dietary intake.

### DISCUSSION:

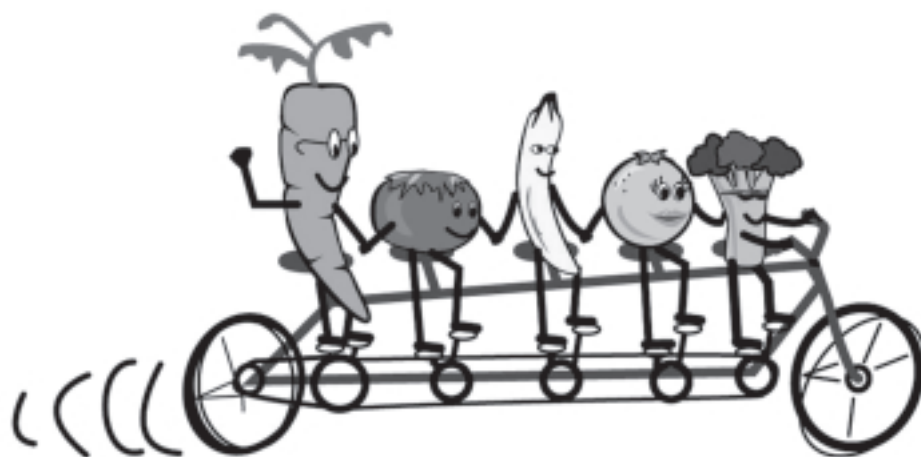
Soybeans are an excellent source of nutrition with its high fiber and unique protein content. When being used in substitute for animal proteins in diet, it can lower cholesterol and triglyceride levels. Its role in other medical conditions are less defined and require further research. Studies on soy extracts and synthetic analogs failed to show any health benefits and the use of these supplements therefore is not recommended. Currently, the most prudent advice to the public is to obtain soybean from whole food such as edamame, tempeh, tofu, etc. The amount consumed should be at least 25 gram of soy protein a day and should be part of an overall healthy life style to minimize all risks of cardiovascular disease.

### THE SOY PROTEIN CONTENT OF SOME COMMON SOYFOODS

SOYFOOD	AMOUNT	PROTEIN CONTENT
FIRM TOFU	3 OUNCES	8.5 GRAMS
REGULAR TOFU	3 OUNCES	6 GRAMS
SOYMILK	8 OUNCES	8 GRAMS
SOYNUTS	1 OUNCE (1/4 CUP)	12 GRAMS
SOYNUT BUTTER	2 TABLESPOON	8 GRAMS
TEMPEH	4 OUNCES (1/2 CUP)	16 GRAM
COOKED/CANNED SOYBEAN	½ CUP	13 GRAMS
GREEN SOYBEAN (EDAMAME)	½ CUP	7 GRAMS
SOY PROTEIN CONCENTRATE	¼ CUP	12 GRAMS
TEXTURED SOY FLOUR	¼ CUP	8 GRAMS
SOY BURGER	1	10 GRAM
SOY BREAKFAST LINKS	2	6.5 GRAMS
SOY BREAKFAST PATTIE	1	6.5 GRAMS

REFERENCES: Available upon request

# It's Fun to be Healthy!



## Every Day

**Eat Five  
Fruits & Vegetables**

**Enjoy  
physical activity**

*A message from the California Department of Health Services.*

## NutritionTimes

The Nutrition Times newsletter is published biannually by the Orange County Nutrition Alert Coalition of the County of Orange Health Care Agency, Nutrition Services Program.

It is intended to keep the public and consumers informed on reliable nutrition information. The coalition is dedicated to the promotion of optimal health and nutrition through consumer education and awareness.

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